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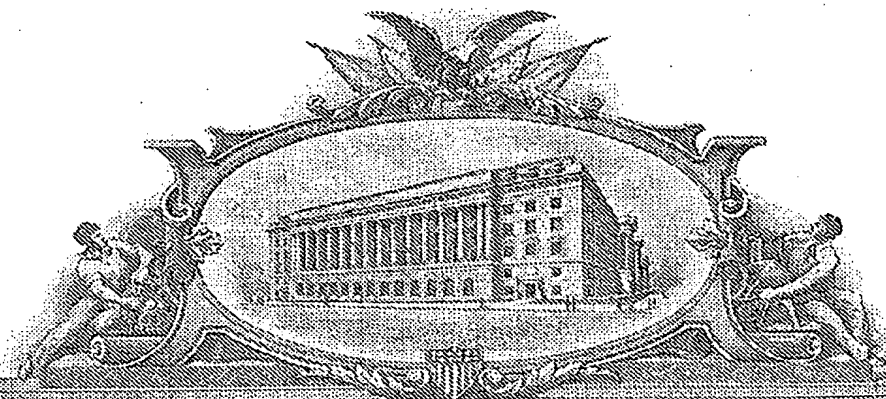
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APPLICATION NUMBER: 60/557,986

FILING DATE: *March 31, 2004*

RELATED PCT APPLICATION NUMBER: *PCT/US05/04454*



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22264 U.S. PTO
60/557986


033104

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Additional inventors are being named on the <u>1</u> separately numbered sheets attached hereto				
TITLE OF THE INVENTION (500 characters max)				
ROLL FORM MEDICAL BANDAGING PRODUCT, MEDICAL BANDAGE MATERIAL, METHOD OF CONSTRUCTING SAME, AND BANDAGING METHOD				
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ENCLOSED APPLICATION PARTS (check all that apply)				
<input checked="" type="checkbox"/> Specification Number of Pages <u>11</u>		<input type="checkbox"/> CD(s), Number _____		
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<input checked="" type="checkbox"/> Application Data Sheet. See 37 CFR 1.76				
METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT				
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.				FILING FEE Amount (\$) <div style="border: 1px solid black; width: 100px; height: 100px; margin: 0 auto; display: flex; align-items: center; justify-content: center;"> \$160.00 </div>
<input type="checkbox"/> A check or money order is enclosed to cover the filing fees.				
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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.				
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[Page 1 of 2]

Respectfully submitted

SIGNATURE

TYPED or PRINTED NAME W. Thad Adams, III

TELEPHONE 704-375-9249

Date 03/31/2004

REGISTRATION NO. 29,037

(if appropriate)

Docket Number: 2765/251

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[Page 2 of 2]

Number 1 of 1

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033104

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FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$ 160.00)

Complete if Known

Application Number

Filing Date

03/31/2004

First Named Inventor

Evans

Examiner Name

Art Unit

Attorney Docket No.

2765/251

METHOD OF PAYMENT (check all that apply)☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None☒ Deposit Account:Deposit
Account
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☒ Charge fee(s) indicated below ☒ Credit any overpayments☒ Charge any additional fee(s) or any underpayment of fee(s)☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.**FEE CALCULATION****1. BASIC FILING FEE**

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description	Fee Paid
1001 770	2001 385	Utility filing fee	
1002 340	2002 170	Design filing fee	
1003 530	2003 265	Plant filing fee	
1004 770	2004 385	Reissue filing fee	
1005 160	2005 80	Provisional filing fee	160

SUBTOTAL (1) (\$ 160)

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims	Extra Claims	Fee from below	Fee Paid
Independent	-20** =	X	
Multiple Dependent	-3** =	X	

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description
1202 18	2202 9	Claims in excess of 20
1201 86	2201 43	Independent claims in excess of 3
1203 290	2203 145	Multiple dependent claim, if not paid
1204 86	2204 43	** Reissue independent claims over original patent
1205 18	2205 9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$ 0)

**or number previously paid, if greater; For Reissue, see above

FEE CALCULATION (continued)**3. ADDITIONAL FEES**

Large Entity Small Entity

Fee Code (\$)	Fee Code (\$)	Fee Description	Fee Paid
1051 130	2051 65	Surcharge - late filing fee or oath	
1052 50	2052 25	Surcharge - late provisional filing fee or cover sheet	
1053 130	1053 130	Non-English specification	
1812 2,520	1812 2,520	For filing a request for ex parte reexamination	
1804 920*	1804 920*	Requesting publication of SIR prior to Examiner action	
1805 1,840*	1805 1,840*	Requesting publication of SIR after Examiner action	
1251 110	2251 55	Extension for reply within first month	
1252 420	2252 210	Extension for reply within second month	
1253 950	2253 475	Extension for reply within third month	
1254 1,480	2254 740	Extension for reply within fourth month	
1255 2,010	2255 1,005	Extension for reply within fifth month	
1401 330	2401 165	Notice of Appeal	
1402 330	2402 165	Filing a brief in support of an appeal	
1403 290	2403 145	Request for oral hearing	
1451 1,510	1451 1,510	Petition to institute a public use proceeding	
1452 110	2452 55	Petition to revive - unavoidable	
1453 1,330	2453 665	Petition to revive - unintentional	
1501 1,330	2501 665	Utility issue fee (or reissue)	
1502 480	2502 240	Design issue fee	
1503 840	2503 320	Plant issue fee	
1460 130	1460 130	Petitions to the Commissioner	
1807 50	1807 50	Processing fee under 37 CFR 1.17(q)	
1806 180	1806 180	Submission of Information Disclosure Stmt	
8021 40	8021 40	Recording each patent assignment per property (times number of properties)	
1809 770	2809 385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810 770	2810 385	For each additional invention to be examined (37 CFR 1.129(b))	
1801 770	2801 385	Request for Continued Examination (RCE)	
1802 900	1802 900	Request for expedited examination of a design application	

Other fee (specify)

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$ 0)

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Date

03/31/2004

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Provisional Patent Application

ROLL FORM MEDICAL BANDAGING PRODUCT,
MEDICAL BANDAGE MATERIAL,
METHOD OF CONSTRUCTING SAME,
AND BANDAGING METHOD

Technical Field and Background of the Invention

[0001] The present invention relates generally to the field of orthopedic medicine and more specifically to the design of an improved medical bandaging product and material formed of a moisture-curable plastic material, a method for constructing such an improved medical bandage, and a method of constructing and applying an improved bandaging product.

[0002] Medical bandages for use in the treatment of injuries, such as broken bones requiring immobilization of a body member, are generally formed from a strip of fabric or scrim material impregnated with a substance which hardens into a rigid structure after the strip has been wrapped around the body member. The hardening substance traditionally used in carrying out this procedure is plaster-of-paris.

[0003] Conventional practice has been to fabricate a cast or splint upon an injured limb by initially applying to the limb a protective covering of a cotton fabric or the like and then overwrapping the covering and limb with a woven cloth impregnated with plaster-of-paris which has been wetted by dipping in water immediately prior to application. This practice is still in widespread use but possesses several significant disadvantages. For example, the above-described application procedure is messy and time consuming. Several components are required and considerable skill is necessary.

[0004] In order to alleviate the above-recited disadvantages of the conventional application procedure for plaster-of-paris casts and splints, unitary splinting materials have been devised and are disclosed in, for example, U.S. Patent Nos. 3,900,024, 3,923,049, and 4,235,228. All of these patents describe a padding material with a

plurality of layers of plaster-of-paris impregnated cloth. Such unitary splinting materials are not as messy and can be applied more quickly but still suffer from a number of disadvantages inherent in plaster-of-paris cast materials. All plaster-of-paris splints have a relatively low strength to weight ratio which results in a finished splint which is very heavy and bulky. Plaster-of-paris splints are slow to harden, requiring 24 to 72 hours to reach maximum strength. Since plaster-of-paris breaks down in water, bathing and showering are difficult. Even if wetting due to these causes can be avoided, perspiration over an extended period of time can break down the plaster-of-paris and create a significant problem with odor and itching.

[0005] A significant advance in the art of casting and splinting is disclosed in U.S. Patent Nos. 4,411,262 and 4,502,479. The casting materials disclosed in these patents comprise a flexible fabric impregnated with a moisture-curing resin enclosed in a moisture-free, moisture-impervious package. Compared to plaster-of-paris, these products are extremely lightweight, have a very high strength to weight ratio and can be made relatively porous, permitting a flow of air through the casting material. Prior art moisture-curing systems include a package within which is contained a plurality of layers of fabric, such as fiberglass, impregnated with a moisture-curing resin. No provision is made for reclosing the package, so that the entire material must be very quickly used after removal from the package since such moisture-curing resins will cure in a relatively short period of time due merely to contact with atmospheric moisture.

[0006] United States Patent Nos. 4,770,299 and 5,003,970, among others owned by applicant, each disclose roll-form synthetic bandaging products which include the ability to dispense desired lengths of bandaging material when needed, while sealing the remaining length of material for later use. These products have proven to be very successful in many applications, since they include a padding material on both sides,

thereby permitting quick and easy application. Similar products are also sold in precut lengths sealed in a single use, moisture impervious envelope.

[0007] From the above discussion, it can be seen that both the conventional plaster-of-paris casting method and the more recent moisture-curable resin casting method possess both advantages and disadvantages. On the one hand, plaster-of-paris casts are bulky, heavy and difficult to apply whereas moisture-curable resin casts are lightweight, durable and relatively easy to apply. Plaster-of-paris can be very easily stored and used as needed since it has a relatively long shelf life so long as it is not completely wetted. On the other hand, the moisture-curable resins are very sensitive to the presence of even minute amounts of moisture which requires that either the materials be packaged in a wide variety of different shapes and sizes or unused portions be discarded, generating a substantial amount of waste and increasing the effective cost of the product.

[0008] Current padded, synthetic roll-form products are, however, relatively expensive and limit the option of the physician to use less padding or padding in different densities or thicknesses from one point on the splint to another.

[0009] This invention combines the advantages of both plaster-of-paris and moisture-curable resin systems while avoiding their respective disadvantages. This is accomplished by providing a unitary splinting system with improved strength and convenience.

[0010] Conventional splinting and casting products have generally been manufactured incorporating textile substrates that have been impregnated with moisture curable resin. These products generally require a knitting process that is often the greater part of the manufacturing process. It has now been determined that an improved fracture support or immobilization product can be made using a polymer foam either independent of or in conjunction with a textile substrate formed by knitting, stitching through, needling,

laminating or bonding. Preferably, in the substrate at least part of the yarns or fibers reach through the polymer foam thus creating a matrix of reinforcement.

Summary of the Invention

[0011] It is therefore an object of the invention to provide a medical bandaging product in roll form with a moisture-curable resin which hardens the material upon exposure to moisture to form a rigid, self-supporting structure.

[0012] It is another object of the invention to provide a medical bandaging product which can be dispensed in any desired length while preventing hardening of the remaining material until use is desired.

[0013] It is another object of the invention to provide an orthopedic immobilizing bandage that can be used as a splint or cast tape which permits a wide variety of padding applications included with, or applied as an integral part of the bandage or to be applied separately.

[0014] According to the present invention, the polymer foam is a pliant-like polymer that is formed either chemically or by physical means. The foam utilized in the invention can be formed from acrylics, nitriles, polyurethane, styrene-butadiene rubber, EVA, PVAC, neoprene, PVDC, PVC, polyolefins like PE or combinations and blends thereof. The structure of the foam can be open cell, closed cell or reticulated cell with a rigid, semi-rigid or flexible hardness. The preferred structure is an open cell foam with between 40-120 pores/opening per inch.

[0015] The primary function of the textile reinforcement is to provide an increased rigidity and durability to the substrate and the final immobilization product. Additionally, the reinforcement helps in reducing the resin weight fraction needed to achieve the desired strength and rigidity.

[0016] These and other objects and advantages of the present invention are achieved in the preferred embodiment disclosed below by providing a medical bandaging product in roll form for being dispensed in predetermined lengths suitable for a given medical use, and comprising an elongate sleeve formed of moisture-impervious material and sealable to prevent entry of moisture, and an elongate medical bandage material substantially the same length as the sleeve and positioned in the sleeve in a single length along the length of the sleeve and sealed therein against entry of moisture until use. The medical bandage material comprises a substrate and a reactive system impregnated into or coated onto the substrate. The system remains stable when maintained in substantially moisture-free conditions and hardens upon exposure to sufficient moisture to form a rigid, self supporting structure. A protective liner sheet encloses the substrate along its length and forms a barrier between the substrate and the sleeve during storage, and is optionally removable after removal of the medical bandage material from the sleeve and prior to application to a patient. The substrate is adapted for having a protective padding material interposed between the substrate and the patient. Resealing means is provided for resealing the sleeve against entry of moisture after a predetermined length of the bandaging product has been dispensed for use to prevent hardening of the substrate remaining in the sleeve.

[0017] According to one preferred embodiment of the invention, the sleeve comprises an aluminum foil laminate having an outer tear resistant layer, a central aluminum foil layer and an inner heat sealable plastic layer.

[0018] According to another preferred embodiment of the invention, the substrate comprises a polymer foam.

[0019] According to yet another preferred embodiment of the invention, the reactive system comprises a blended polyisocyanate, polyol, catalyst and stabilizer.

[0020] According to yet another preferred embodiment of the invention, the resealing means for resealing the sleeve is selected from the group consisting of tape, a clamp, a clip for holding a folded end of the sleeve closed and a restricted opening through which the sleeve is extended.

[0021] According to yet another preferred embodiment of the invention, the roll comprises the sleeve with the medical bandage material therein and the sleeve formed into a coil.

[0022] Preferably, the invention includes a dispenser within which the coil of bandaging material is contained.

[0023] According to yet another preferred embodiment of the invention, the dispenser comprises a container within which the roll is positioned, the container defining a slot therein in which the leading end of the coil may be positioned and through which the product is dispensed as needed.

[0024] According to yet another preferred embodiment of the invention, a medical bandaging product is provided for being packaged in predetermined lengths suitable for a given medical use, and comprises a sleeve formed of moisture-impervious material and sealable to prevent entry of moisture and a medical bandage material positioned in the sleeve and sealed therein against entry of moisture until use. The medical bandage material comprises a substrate, a reactive system impregnated into or coated onto the substrate, the system remaining stable when maintained in substantially moisture-free conditions and hardening upon exposure to sufficient moisture to form a rigid, self supporting structure. A protective liner sheet encloses the substrate and forms a barrier between the substrate and the sleeve during storage and is optionally removable after removal of the medical bandage material from the sleeve and prior to application to a patient. The substrate is adapted for having a protective padding material interposed between the substrate and the patient.

[0025] According to yet another preferred embodiment of the invention, a medical bandaging product having a predetermined length suitable for a given medical use is provided, and comprises an enclosure formed of a moisture-impervious material sealable to prevent entry of moisture. The enclosure includes an elongate, resealable dispensing sleeve with a medical bandage material positioned in the enclosure and sealed therein against entry of moisture until use. The medical bandage material comprises a substrate formed of a plurality of knitted or woven fabric layers, a reactive system impregnated into or coated onto the substrate, the system remaining stable when maintained in substantially moisture-free conditions and hardening upon exposure to sufficient moisture to form a rigid, self-supporting structure and comprising a blended polyisocyanate, polyol, catalyst and stabilizer.

[0026] An embodiment of the method of constructing a medical bandaging product according to the invention comprises the steps of providing an elongate, moisture-impervious sleeve and an elongate medical bandage material comprised of a substrate enclosed within a padding layer, impregnating into or coating onto the substrate a reactive system which remains stable when maintained in substantially moisture-free conditions and hardens upon exposure to sufficient moisture to form a rigid, self-supporting structure, and positioning a length of the elongate medical bandage material within the elongate sleeve which is generally the same length as the sleeve and which extends along the length of the sleeve in a single layer. The sleeve is sealed to prevent entry of moisture until use.

Brief Description of the Drawings

[0027] Some of the objects of the invention have been set forth above. Other objects and advantages of the invention will appear as the description of the invention proceeds when taken in conjunction with the following drawings, in which:

[0028] Figure 1 is a perspective view of an embodiment of the medical bandaging product including a moisture-impervious foil sleeve;

[0029] Figure 2 is a perspective view of a length of the medical bandaging material;

[0030] Figure 3 is a vertical cross-sectional view of the medical bandaging material shown in Figure 2;

[0031] Figure 4 is a perspective view of the medical bandaging product, including an embodiment of the dispensing box;

[0032] Figure 5 is a perspective view of the medical bandaging product shown in Figure 5, showing the manner of closing the foil sleeve after use;

[0033] Figures 6 and 7 illustrate a preferred manner of preparing and applying the medical bandage material according to the invention.

Description of the Preferred Embodiment and Best Mode

[0034] Referring now specifically to the drawings, a medical bandaging product according to the present invention is illustrated in Figure 1 and shown generally at reference numeral 10. The medical bandaging product 10 is comprised of a substrate 12, coated or impregnated with a moisture-curable resin as described more specifically below, enclosed within a soft padding 15, such as nonwoven polypropylene. The substrate 12 and padding 15 together comprise a medical bandaging material 16. The medical bandaging material 16 is enclosed within a laminated foil/plastic sleeve 18 in moisture-free conditions and sealed within the sleeve 18 to maintain the moisture-free conditions until the product is ready for use.

[0035] The substrate 12 is preferably made using a polymer foam either independent of or in conjunction with a textile substrate formed by knitting, stitching through, needling, laminating or bonding. Preferably, in the substrate at least part of the yarns or fibers reach through the polymer foam thus creating a matrix of reinforcement.

[0036] According to the present invention, the polymer foam is a pliant-like polymer that is formed either chemically or by physical means. The foam utilized in the invention can be formed from acrylics, nitriles, polyurethane, styrene-butadiene rubber, EVA, PVAC, neoprene, PVDC, PVC, polyolefins like PE or combinations and blends thereof. The structure of the foam can be open cell, closed cell or reticulated cell with a rigid, semi-rigid or flexible hardness. The preferred structure is an open cell foam with between 40-120 pores/opening per inch.

[0037] The primary function of the textile reinforcement is to provide an increased rigidity and durability to the substrate and the final immobilization product. Additionally, the reinforcement helps in reducing the resin weight fraction needed to achieve the desired strength and rigidity. The fibers or yarns used to stitch, knit through, needle, laminate or bond to the foam may be any suitable organic or inorganic fiber such as polyester, polypropylene, polyethylene, cotton, nylon, aramid yarns or fibers, wool, flax, jute and glass or any other synthetic material. The count of fibers should be in the range of 100 to 2000 dtex, preferably 250-1500 dtex. The construction of the reinforced substrate with knitting, stitching or needling should allow for a spacing of thread in the length or warp direction of between 5 and 50 per inch, more preferably between 12 and 24 per inch.

[0038] The weight of the total substrate is not limited but should be in the range of 20-500 g/m², most preferably 20-250 g/m². The foam substrate should preferably have a thickness of between 0.5mm to 6mm, more preferably 4mm. Foams in excess of this value tend to be too thick for conforming to the human anatomy and create a bulky immobilization device. In this regard, an open cell foam is the preferred option with approximately 20-150 pores per inch, more preferably 65-85 pores per inch.

[0039] In another embodiment, the foam can be reinforced by adding an organic or inorganic filler during manufacturing of the foam, or an external organic or inorganic

filler such as wood flour, chopped fibers, glass, silica, microfibers, microspheres in the foam substrate to attain the desired strength and rigidity levels. Addition of fillers may also help in improving the breathability and porosity of the foam substrate. Addition of lower density fibers or microspheres will also help in reducing the weight of the final product. The filler loading will depend on the type of filler chosen and the final rigidity value desired. Preferred filler loading can vary in the range of 15-85 percent by volume.

[0040] Typically the reinforced foam substrate that has been knitted through, needled into, laminated or bonded with textile fibers or yarns or loaded with fillers will be impregnated with a curable resin, more preferably an isocyanate resin that can be cured by air or water.

[0041] Substrate 12 is impregnated or coated with a reactive system which remains stable when maintained in substantially moisture-free conditions but which hardens upon exposure to sufficient moisture to form a rigid, self-supporting structure. A typical formulation of the reaction system is set forth in the following table:

Typical Formulation:

Isonate 143L or
Mondur CD or
Polysiocyanate 50.0%
Carbowax PEG 600
Carbowax PEG 4600
Carbowax PEG 8000
Voranol 230-238
Voranol 220-110
Irganox 1010
Antifoam 1400
Methane Sulphonic Acid
DMDEE

[0042] A complete discussion of the parameters of the reactive system, the manner of production and the variables which apply are found in U.S. Patent No. 4,411,262.

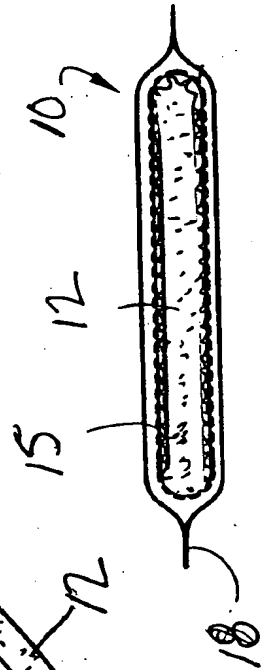
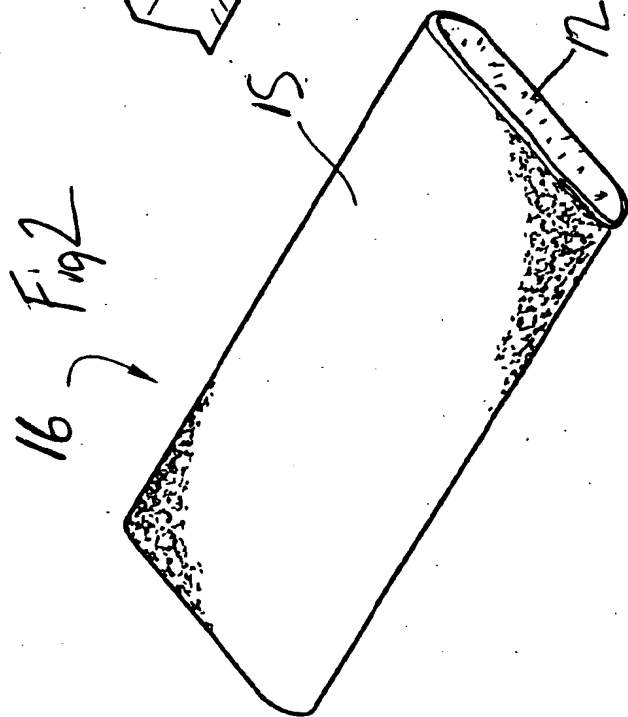
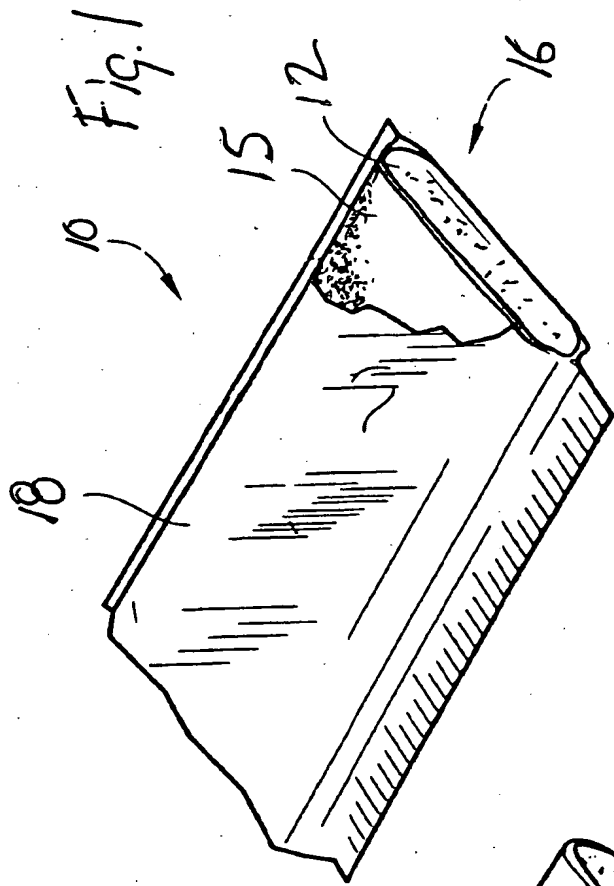
[0043] The polyisocyanate resin remains in a viscous state as long as the resin is not exposed to moisture. This permits the substrate to remain flexible and moldable so

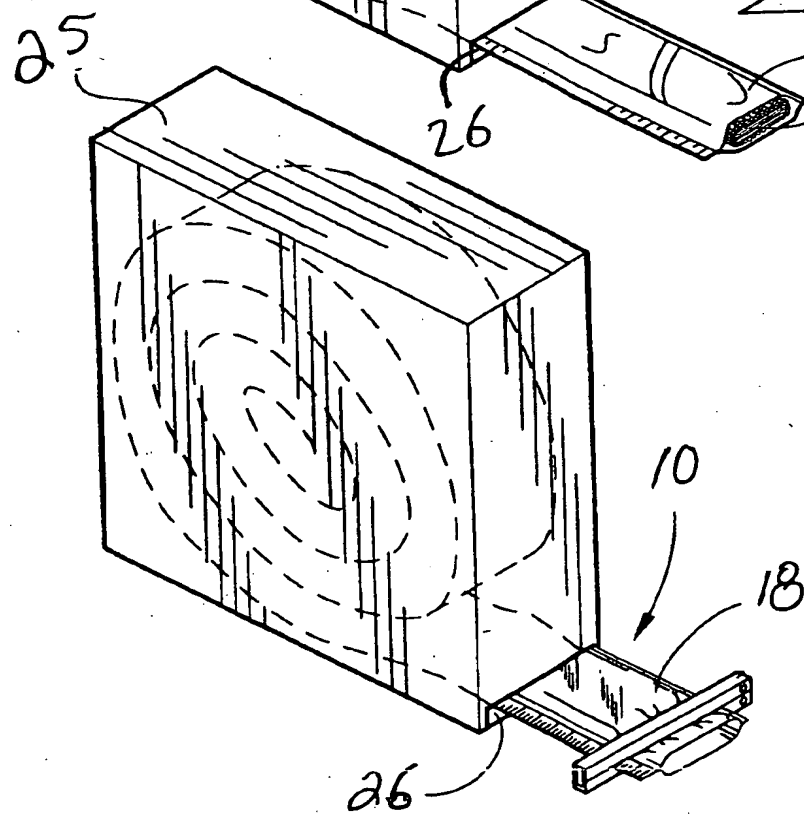
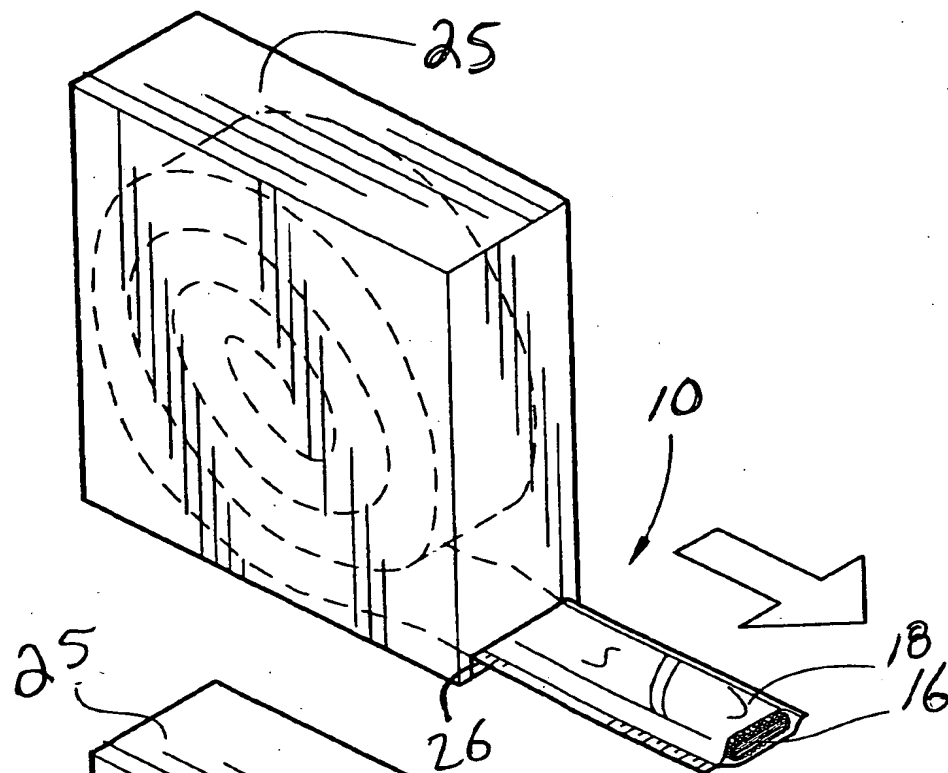
long as the resin is not exposed to moisture, and for a short period of time after such exposure occurs. The rate at which the resin cures can be controlled to some extent by the quantity of water to which the resin is exposed. Briefly immersing the resin in water will cause the resin to rapidly cure. In contrast, merely exposing the resin to open air will result in a curing process having a significantly slower reaction rate which will be proportional to the amount of moisture in the air to which the resin is exposed.

[0044] Medical bandaging product 10 may be sold in any convenient length, such as 24 feet, and is rolled into a coil and positioned in a suitable dispensing box 25, as is shown in Figures 4 and 5. Dispensing box 25 is provided with a slot 26 at one lower corner through which bandaging product 10 extends.

[0045] As is shown in Figures 6 and 7, a length of the medical bandaging material 16, after having been dispensed from the box 25, removed from the foil sleeve 18 and wetted as described above, is applied to the limb to be treated and molded into a conformable shape. An elastic bandage "B" is then applied over the material 16 to hold the material 16 in its conformed shape during hardening. This occurs over a period of several minutes, depending on the amount of moisture to which the resin was exposed. Upon hardening, the medical bandaging material 16 forms a splint that is maintained on the limb with the bandage "B" during healing, but which can be removed as needed for bathing or splint replacement.

[0046] A medical bandaging product and material formed of a moisture-curable plastic material, a method for constructing such an improved medical bandage, and a method of constructing and applying an improved bandaging product is described above. Various details of the invention may be changed without departing from its scope. Furthermore, the foregoing description of the preferred embodiment of the invention and the best mode for practicing the invention are provided for the purpose of illustration only and not for the purpose of limitation.





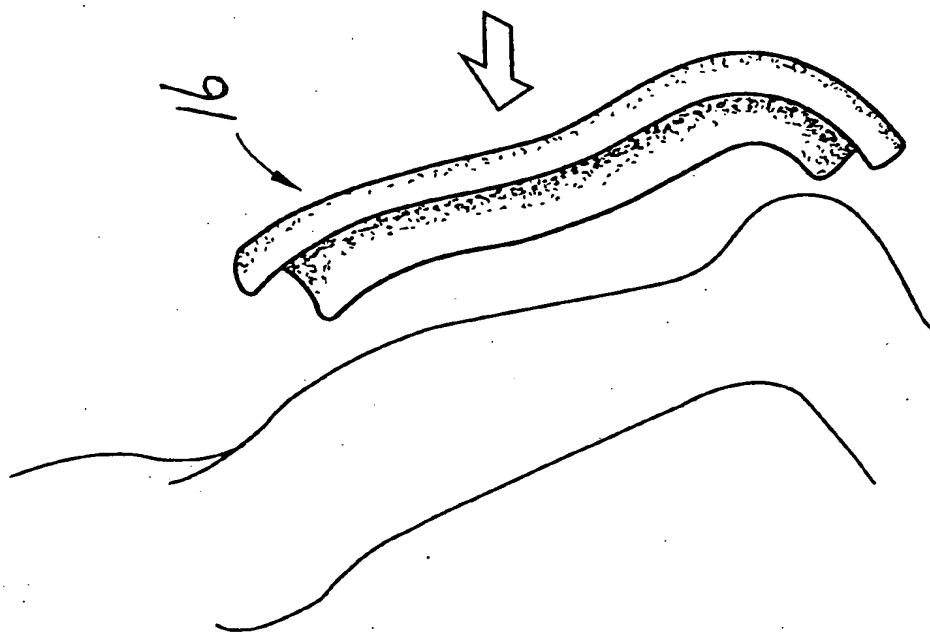


Fig 6

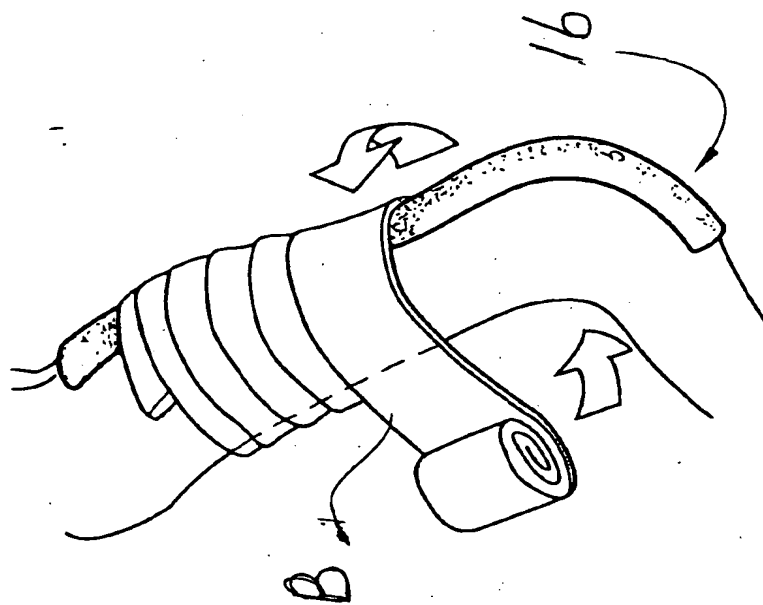


Fig 7

Application Data Sheet

Application Information

Application Type::	Regular
Subject Matter::	Provisional
CD-ROM or CD-R?::	None
Title::	ROLL FORM MEDICAL BANDAGING PRODUCT, MEDICAL BANDAGE MATERIAL, METHOD OF CONSTRUCTING SAME, AND BANDAGING METHOD
Attorney Docket Number::	2765/251
Total Drawing Sheets::	3
Small Entity?::	No
Petition included?::	No
Secrecy Order in Parent Appl?::	No

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